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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/545,283	04/07/2000	Bryan J. Boyle	HYS-5	1585

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ART UNIT	PAPER NUMBER
1634	14

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/545,283	Boyle et al
Examiner	**Art Unit**
Jehanne Souaya	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Nov 19, 2001 .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 10, 11, 16-18, 20, 30, and 31 is/are pending in the application.

4a) Of the above, claim(s) 16-18 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 10, 11, 20, 30, and 31 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on Apr 7, 2000 is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☒ Interview Summary (PTO-413) Paper No(s). 14

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Note: The art unit designation for the examiner has changed from 1655 to 1634.

The hand carried copy (received 1/30/02) of the Corrected Sequence Listing and Disk mailed 1/18/2001 have been received and entered. The corrected disk was found to be in compliance.

The preliminary amendment filed 11/19/2001 has been received and entered. Claims 1-9, 12-15, 19, and 21-29 have been canceled. Claims 10-11, 16-18, 20, and newly added claims 30-31 are pending in the instant application. Support for newly added claim 30 is found at page 6, line 11 of the specification.

Election/Restriction

1. Applicant's election to the restriction requirement of 5/18/2001 of Group III, claims 10-11, 16-18, 20 and 25-26 (canceled) is acknowledged, SEQ ID NOS 3, 4 and 6. Upon further review, the examiner has set forth a further restriction requirement to these elected claims:

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

III. Claims 10-11, 20, and newly added claims 30-31, drawn to polypeptides, classified in class 530, subclass 350.

VI. Claims 16-18, drawn to methods for detecting polypeptides and to methods for identifying compounds that bind to polypeptides, classified in class 435, subclass 7.1.

Brief description of Groups outlined in the previous office action of 5/18/01 (see previous office action for a detailed description of each group):

I. Claims 1-9, 13-15, 19, and 27-29 drawn to polynucleotides.
II. Claims 21-23 drawn to nucleic acid arrays.
IV. Claim 12 drawn to antibodies.
V. Claim 24 drawn to methods of treating.

The inventions are distinct, each from the other because of the following reasons:

Regarding the invention of Group III:

3. As set forth in the previous restriction requirement, the invention of group III is patentably distinct from the inventions of groups I and IV as they are drawn to patentably distinct products (see section 3 of Office Action mailed 5/18/01). The invention of group III is patentably distinct from the invention of group II as the inventions are unrelated (see section 4 of Office action mailed 5/18/01). The invention of group III is patentably distinct from the invention of group V (see section 5 of 5/18/01 office action) as the method of treatment of Group V is unobvious over the polypeptides of Group III and further the polypeptides of Group III can be used to make fusion proteins.

4. The inventions of Groups III and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of group III can be used to make fusion proteins.

Regarding the invention of Group VI:

5. The inventions of Groups VI and I, II, & V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions of Groups I and II are not used in the methods of Group VI. Furthermore, the inventions of Groups V and VI are not usable together as the method of group VI is directed to detecting a polypeptide or a compound that binds a polypeptide while the method of group V is directed to methods of treatment. The methods of Groups V and VI have different modes of operation.

6. The inventions of Groups VI and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of Group VI can be carried out using a ligand that binds to the polypeptide in the method of Group VI, that is materially different, structurally and functionally, than an antibody of Group IV.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

9. During a telephone conversation with Nicholas Triano on February 11, 2001 a provisional election was made without traverse to prosecute the invention of Group III, claims 10-11, 20 and 30-31. Affirmation of this election must be made by applicant in replying to this Office action.

Priority

10. Applicant's claim for priority to application 09/496,914, filed 2/3/2000, is acknowledged. However, the currently pending claims under consideration, 10-11, 20, and 30-31, have not been awarded the benefit of the earlier filing date of the '914 application as the subject matter in the claims is not disclosed in the '914 application.

Drawings

11. The drawings are objected to because the number designation in each figure for SEQ ID NO 4 does not match the number of the amino acid in the sequence listing. The figures are confusing, for example, Fig 1 seems to suggest that SEQ ID NO 4 has at least 696 amino acids, however, the specification and the sequence listing show that it is a 234 amino acid polypeptide.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 101

Definitions: [from REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS; repeated from http://www.uspto.gov/web/menu/utility.pdf]

"Credible Utility" - Where an applicant has specifically asserted that an invention has a particular utility, that assertion cannot simply be dismissed by Office personnel as being "wrong". Rather, Office personnel must determine if the assertion of utility is credible (i.e., whether the assertion of utility is believable to a person of ordinary skill in the art based on the totality of evidence and reasoning provided). An assertion is credible unless (A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based is inconsistent with the logic underlying the assertion. Credibility as used in this context refers to the reliability of the statement based on the logic and facts that are offered by the applicant to support the assertion of utility. A credible utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for such use. For example, no perpetual motion machines would be considered to be currently available. However, nucleic acids could be used as probes, chromosome markers, or forensic or diagnostic markers. Therefore, the credibility of such an assertion would not be questioned, although such a use might fail the specific and substantial tests (see below).

"Specific Utility" - A utility that is specific to the subject matter claimed. This contrasts with a general utility that would be applicable to the broad class of the invention. For example, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be specific in the absence of a disclosure of a specific DNA target. Similarly, a general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed.

"Substantial utility" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a "substantial utility" define a "real world" context of use. An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring. On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":

A. Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved.

B. A method of treating an unspecified disease or condition. (Note, this is in contrast to the general rule that treatments of specific diseases or conditions meet the criteria of 35 U.S.C. ' 101.)

C. A Method of assaying for or identifying a material that itself has no "specific and/or substantial utility."

D. A method of making a material that itself has no specific, substantial, and credible utility.

E. A claim to an intermediate product for use in making a final product that has no specific, substantial, and credible utility.

Note that "throw away" utilities do not meet the tests for a specific or substantial utility. For example, using transgenic mice as snake food is a utility that is neither specific (all mice could function as snake food) nor substantial (using a mouse costing tens of thousands of dollars to produce as snake food is not a "real world" context of use). Similarly, use of any protein as an animal food supplement or a shampoo ingredient are "throw away" utilities that would not pass muster as specific or substantial utilities under 35 U.S.C. ' 101. This analysis should, or course, be tempered by consideration of the context and nature of the invention. For example, it a transgenic mouse was generated with the specific provision of an enhanced nutrient profile, and disclosed for use as an animal food, then the test for specific and substantial asserted utility would be considered to be met.

A "Well established utility" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. "Well established utility" does not encompass any "throw away" utility that one can dream up for an invention or a nonspecific utility that would apply to virtually every member of a general class of materials, such as proteins or DNA. If this is the case, any product or apparatus, including perpetual motion machines, would have a "well established utility" as landfill, an amusement device, a toy, or a paper weight; any carbon containing molecule would have a "well established utility" as a fuel since it can be burned; any protein would have well established utility as a protein supplement for animal food. This is not the intention of the statute.
See also the MPEP at 2107 - 2107.02.

12. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

13. Claims 10-11, 20, and 30-31 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

The claims are drawn to isolated polypeptides comprising the amino acid sequence of SEQ ID NOS 4 or 6, to compositions and kits comprising these polypeptides, to an isolated polypeptide comprising an amino acid which is 99% identical to the amino acid sequence of SEQ ID NO 4 or 6, and to a polypeptide encoded by a polynucleotide comprising the sequence of SEQ ID NO 3. The specification teaches that SEQ ID NO 4 is a C-type lectin receptor like

polypeptide. SEQ ID NO 4 corresponds to the amino acid sequence encoded by the nucleic acid of SEQ ID NO 3. The specification teaches that SEQ ID NO 6 is the extracellular portion of SEQ ID NO 4 (see p. 4, lines 28). The specification further teaches that a predicted N-linked glycosylation site is encoded between residues 110 and 112 (Arg His Trp) of SEQ ID NO 4 (p. 4, lines 29-30). The specification, however does not teach the activity or biological function of SEQ ID NOS 3, 4, or 6. At page 4, line 28, the specification asserts that SEQ ID NO 6 is useful on its own as a soluble protein, but does not disclose what this use is, teaching only that this can be confirmed by expression in mammalian cells and sequencing of cleaved product.

The specification asserts the following uses for the polypeptides. At page 7, lines 23-29, the specification teaches that the polypeptides can be used a) to generate an antibody that specifically binds the polypeptide, b) as molecular weight markers, and c) as food supplements. The specification further asserts that the polypeptide can be used to prevent, treat, or ameliorate a medical condition (sentence bridging pages 7 and 8, and page 8 first para) which involve aberrant protein expression or biological activity. The specification asserts that the polypeptides of the invention having C-type lectin receptor activity are useful for prophylaxis or treatment of disorders or diseases caused by or involving allergic reactions, inflammation, sepsis, Alzheimer's disease or other nervous system disorders, bone development, and wound healing (p. 8, lines 26-30). At page 45, lines 5-10, the specification asserts that the polypeptides can also be used in assays to determine biological activity, to raise antibodies or to elicit an immune response, as a reagent in assays designed to quantitatively determine levels of the protein in biological fluids,

and to isolate correlative receptors or ligands. The claimed polypeptides, however, are not supported by a specific asserted utility because the disclosed uses of the polypeptides are non specific uses that are applicable to polypeptides in general and not particular or specific to the polypeptide being claimed. It is noted that the specification asserts that SEQ ID NO 4 may function as a shed receptor, however the specification has not demonstrated such nor is this use specific for SEQ ID NO 4 as a number of other receptors have such a function including IL-2R, TNF-alpha receptor, EPCR (endothelial cell protein receptor) and peritoneal macrophage Fc gamma receptor. The fact that a receptor may be shed does not make clear or apparent the function or specificity of the receptor, nor does it identify the ligand for the receptor.

Further, the claimed polypeptides are not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. For example, a polypeptide can be used to obtain an antibody. The antibody could then be used in conducting research to functionally isolate the protein. The need for such research clearly indicates that the protein and/or its function is not disclosed as to a currently available or substantial utility. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case, none of the antibodies that are to be produced as final products resulting from processes involving claimed polypeptides have specific and substantial utilities. The research contemplated by applicant(s) to characterize potential protein products, especially their biological activities, does not constitute a specific and substantial utility. Identifying and studying the properties of a

protein itself or the mechanisms in which the protein is involved does not define a "real world" context of use. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility of the utility has not been assessed.

It is noted that the specification teaches that SEQ ID NO 4 has 39% identity to "mouse macrophage C-type lectin" over amino acids 18-232 of SEQ ID NO 4, 49% identity to "dendritic cell immunoreceptor" and "DDB27" (which appear to be the same protein) over amino acids 39-227 of SEQ ID NO 4, and 44% identity to "mouse C-type" over amino acids 16 to 225 of SEQ ID NO 4 (p. 4). The specification further asserts the C-type lectin receptor-like proteins of the invention belong to the same family as C-type lectin receptor, mannose-binding lectins, mammon-binding lectins, and dendritic cell immunoreceptors and therefore have similar activity to these C-type lectin receptor proteins. C-type lectin receptors, however, belong to a large family of proteins exhibiting different structures and functions, such that an analysis based solely on homology or membership in a broad family does not identify the ligand or biological activity or function of SEQ ID NO 4. Akimoto et al teach (Akimoto, Y, et al. Prog. Histochem. Cytochem. 1998, vol. 33, pp 1-92) that C-type lectins are a family of lectins that have a common type of carbohydrate recognition domain (CRD), however they perform diverse biological functions including clearance of molecules from blood circulation (hepatocyte asialoglycoprotein

receptors), internalization of foreign and self derived materials, (alveolar macrophage lectin), role in humoral self defense mechanisms (collectins), cell-cell adhesion (selectins), and transmembrane signaling to cells (natural killer cell receptors) (p. 12, section 2.2). With regard to the CRD, Drickamer (Curr. Opin. Struct. Biol., 1999, vol. 9, pp 585-590) teaches that evidence in the art suggests that many protein modules containing part or all of the C-type CRD motif serve functions other than saccharide recognition, and that it is appropriate to consider this motif a characteristic of C-type lectin-like domains to reflect their similarity to CRDs of C-type lectins without necessarily implying common function (p. 585, col. 1, para 2). Figure 3 of Akimoto et al illustrates the differences in structural organization of C-type lectins, and table 3, teaches the variety of different ligands and sugars for which different C-type lectins exhibit specificity. This wide range of sugars and ligands include galactose, N-acetylgalactoseamine (GalNAc), glucose, fucose, N-acetylglucosamine (GluNAc), mannose, sulfated polysaccharides, and IgE for example. It is further noted that the specification asserts that SEQ ID NO 4 has similar activity to different types of C-type lectin receptors, including mannose binding lectins which belong to the collectin subfamily, while the "dendritic cell immunoreceptor" and "mouse macrophage C-type lectin", which the specification teaches a certain % identity to SEQ ID NO: 4, appear to belong to the type II receptors. From the teachings of Akimoto, however, it is apparent that assignment of SEQ ID NO 4 to a particular subfamily does not make apparent the function or specificity of SEQ ID NO 4 as table 3 shows that different type II receptors have different

specificities and bind different ligands. For example human H1 binds galactose and N-acetylgalactoseamine while CD23 binds IgE.

Furthermore, with regard to the alignment of SEQ ID NO 4 with "mouse macrophage C-type lectin" and "dendritic cell immunoreceptor", for example, the art does not teach the function or specificity for either receptor. Balch et al (JBC, 1998, vol. 273, pp 18656-18664) teaches that comparative sequence analysis suggests that "mouse macrophage C-type lectin" (referenced as mMCL by Balch) has carbohydrate binding capabilities, but that little can be postulated about the ability or specificity of mMCL from its protein sequence alone because even within a relatively small, conserved domain, binding specificity can be altered with the mutation of only one or two amino acids (see Iobst and Drickamer, JBC, 1994, vol. 269, pp 15512-15519). Balch further teaches that some molecules containing C-type lectin domains have been shown to bind peptide sequences such that this versatility makes predicting putative ligands for this type of lectin domain difficult, and that for mMCL this task is even more challenging because a serine rather than the typically conserved proline separates the two critical sugar binding residues corresponding to Glu-185 and Asn-187 (p. 18662, paragraph bridging col. 1 and 2). Bates et al (J. Immunol., 1999, vol. 162, pp 1973-1983) teach that dendritic cell immunoreceptor (DCIR) is a type II membrane glycoprotein (abstract) and that it is of potential importance in regulation of dendritic cell function, however it's function or activity in such regulation is not taught. Bates teaches that the Ca^{2+} ligating residues are well conserved in DCIR, displaying closest homology with hepatic ASG-PR, but that localization of the gene on chromosome 17 could suggest that

DCIR represents an evolutionary intermediate between the NK cell receptors and the hepatic lectins [different type II lectins - see Akimoto et al] and that the cytoplasmic domain of DCIR contains one ITIM motif which is present in the cytoplasmic tail of C-type lectin like molecules expressed by NK cells (p. 1979, col. 2, last two sentences of last full para; and bridging para pp 1979-1980). A sequence search of SEQ ID NO 4 revealed 43.5 % identity to dectin 2, a C-type lectin, however studies showed that a his-dectin 2 fusion protein failed to exhibit specific binding to mannose, fucose, lactose, GluNAc or GalNAc (Ariizumi et al, JBC, 2000, vol. 275, pp 11957-11963; p. 11960, col. 2, last full para.). Therefore the indicated % identity and similarity to C-type lectin receptors would not indicate to one of skill a specific or substantial utility for the claimed polypeptides. While it is credible that SEQ ID NO 4 belongs to the C-type lectin receptor family, the prediction of putative domains does not provide the artisan with a "real world" use for the claimed polypeptides. The specification does not teach what the biological activity or function of SEQ ID NO 4 is, nor does it demonstrate which diseases it is associated with or would be used to treat. Therefore, the citation of sequence similarity results in an unpredictable and therefore unreliable correspondence between the claimed biomolecule and the indicated similar biomolecules and therefore lacks support regarding utility. Further experimentation would be required of the skilled artisan to determine a use for the polypeptides of the claimed invention. As noted by Brenner v. Manson, 383 US 519, 535-536 (1996), "Congress intended that no patents be granted on a chemical compound whose sole "utility"

consists of its potential role as an object of use - testing... a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."

Claim Rejections - 35 USC § 112

Enablement

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-11, 20, and 30-31 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The teachings in the specification are set forth above (section 13). Given that the art teaches the unpredictability of determining function and specificity with regard to C-type lectins based on homology analysis alone, and that the specification does not teach the activity or function of the claimed molecules, the skilled artisan would have to perform trial and error to determine the function and activity of the claimed molecules, the results of which are unpredictable, thus constituting undue experimentation.

Written Description

15. Claims 10-11, 20, and 30-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

With regard to claims 10-11, 20, and 31, the claims are drawn to polypeptides that comprise the amino acid sequence of SEQ ID NOS 4 or 6 and to a polypeptide encoded by a polynucleotide comprising SEQ ID NO 3. Such a recitation encompasses the full length protein containing SEQ ID NOS 4 or 6, and to a full length protein encoded by a full length cDNA open reading frame containing SEQ ID NO 3. The specification, however, does not teach that SEQ ID NO 3 is a full length cDNA open reading frame. At page 32, the specificaiton teaches that isolated polypeptides of the invention can include an amino acid sequence encoded by any of the nucleotide sequences of SEQ ID NO 1-3 *or the corresponding full length or mature protein*. At page 110, the specification teaches that assembly of the novel nucleotide sequence of SEQ ID NO 3 was accomplished by using an EST sequence SEQ ID NO 1 as a seed and that the seed was extended by using software programs such as BLAST and Hyseq proprietary software to pull additional sequences and by gel sequencing using primers to extend both 5' and 3' ends. At page 21, the specification teaches that isolated polynucleotides of the invention can include a polynucleotide comprising the full length protein coding sequence of the polynucleotide of SEQ ID NO 3, and polynucleotides *comprising* the nucleotide sequence encoding the mature protein coding sequence of the polynucleotide of SEQ ID NO 3 (lines 26-31). Thus from this recitation, the specification is unclear as to whether SEQ ID NO 3 corresponds to a full length cDNA open reading frame and consequently whether SEQ ID NO 4 corresponds to a full length protein.

Thus, if SEQ ID NO 3 is not a full length cDNA open reading frame, the claims encompass variants of SEQ ID NO 4 which are not taught in the specification. As the function or activity of SEQ ID NO 4 is not taught in the specification, and the recitation of sequence similarity in the specification does not make clear the function of SEQ ID NO 4, the disclosed structure of SEQ ID NO 4 is not representative of the genus of polypeptides encompassed by the claimed invention.

With regard to claim 30, the claim is drawn to a polypeptide sequence which is 99% identical to the amino acid of SEQ ID NO 4 or SEQ ID NO 6. Such a recitation encompasses mutants of SEQ ID NO 4 or 6 as well as variants of SEQ ID NOS 4 or 6 without altered function. The specification, however, does not teach what the function or activity of SEQ ID NO 4 or 6, nor does the specification teach which amino acids can be altered such that the function of SEQ ID NO 4 or 6 are altered, or remain intact. The specification only teaches that SEQ ID NO 4 possesses sequence identity to a few C-type lectin like receptors and asserts the C-type lectin receptor-like proteins of the invention belong to the same family as C-type lectin receptor, mannose-binding lectins, mammon-binding lectins, and dendritic cell immunoreceptors and therefore have similar activity to these C-type lectin receptor proteins. C-type lectin receptors, however, belong to a large family of proteins exhibiting different structures and functions, such that an analysis based solely on homology or membership in a broad family does not identify the ligand or biological activity or function of SEQ ID NO 4. Balch et al (JBC, 1998, vol. 273, pp 18656-18664) teaches that comparative sequence analysis suggests that "mouse macrophage C-

type lectin" (referenced as mMCL by Balch, and which possesses 39% amino acid identity to SEQ ID NO 4) has carbohydrate binding capabilities, but that little can be postulated about the ability or specificity of mMCL from its protein sequence alone because even within a relatively small, conserved domain, binding specificity can be altered with the mutation of only one or two amino acids (see Iobst and Drickamer, JBC, 1994, vol. 269, pp 15512-15519). Balch further teaches that some molecules containing C-type lectin domains have been shown to bind peptide sequences such that this versatility makes predicting putative ligands for this type of lectin domain difficult. Therefore, since the specificity, biological activity or function of SEQ ID NOS 4 or 6 have not been taught, and the art clearly teaches that homology analysis alone does not make clear the function of a C-type lectin receptor, the recitation of 99% identity encompasses mutants and variants that have not been described by the specification. The recitation of the amino acid sequences of SEQ ID NOS 4 and 6 is not representative of the functionally different proteins from this broad class, nor do the teachings in the specification make clear to the skilled artisan which amino acids can be changed to result in either a protein with similar or altered activity to the polypeptides of SEQ ID NOS 4 or 6.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of

ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of polypeptides consisting of SEQ ID NOS: 4 and 6 or a polypeptide encoded by a polynucleotide consisting of the sequence of SEQ ID NO 3, the skilled artisan cannot envision the detailed chemical structure of the encompassed proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for making or isolating it. The polypeptide itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

Accordingly, the specification does not provide a written description of the invention of claims 10-11, 20, and 30-31.

Indefinite

16. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

17. Claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of 'the polynucleotide" lacks sufficient antecedent basis. This rejection can be overcome by reciting instead "a polynucleotide".

Conclusion

18. No claims are allowable.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya
Patent examiner
Art Unit 1634
Jehanne Souaya
Feb. 22, 2002